



International Alliance for
Biological Standardization

12th Annual Statistics Workshop: From Data to Patients – CMC Statisticians' Contributions to Quality, Safety, and Efficacy of Pharmaceutical Products

**October 20-22, 2026
Rockville, U.S.A.**

Considerations for Bayesian-Informed CMC Regulatory - Jun Gao, BRDD / Health Canada

Bayesian methodology can be applied, where appropriate, to integrate historical or prior knowledge with new data to update estimates of a product or quality attribute in Chemistry, Manufacturing, and Controls (CMC) assessments. As interest in these Bayesian methods continues to grow, collaboration among industry and regulators can help advance their effective use in CMC development and regulatory submissions.

This presentation will share emerging perspectives from quality and statistical reviewers within Health Canada's Biologic and Radiopharmaceutical Drugs Directorate (BRDD) regarding the quality review of Bayesian-informed CMC submissions.

The discussion will explore how Bayesian approaches can support CMC decision-making, with particular attention to the thoughtful use of prior information, the connection between statistical modelling and process knowledge, and the interpretation of results within the broader scientific context.

Effective reporting can facilitate multidisciplinary understanding and constructive dialogue between sponsors and regulators. Some thoughts on reporting Bayesian analyses will also be shared, including clear descriptions and/or justification of the CMC objective, current and historical data and information, prior distributions, modelling assumptions, posterior results, diagnostic assessments, and sensitivity analyses.

Finally, two successful submissions will illustrate how Bayesian approaches have been used in quality submissions. These examples will highlight the importance of early collaboration, transparent communication, and integration of statistical evidence with product and process knowledge. Overall, the presentation aims to encourage continued dialogue and support the appropriate use of Bayesian methods in CMC development and regulatory decision-making.

